September 20, 2021

Advanced Medical Optics, Inc.
Ms. Kim Regis
Manager, Regulatory Affairs Projects
1700 East St. Andrew Pl.
Santa Ana, California 92705

Re: K081545
Trade/Device Name: ONE SERIES™ Ultra Cartridges
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I, reserved
Product Code: MSS

Dear Ms. Kim Regis:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 2, 2008. Specifically, FDA is updating this SE Letter to include the correct product code as an administrative correction. Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Bennett Walker, Ph.D., OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-5094, bennett.walker@fda.hhs.gov .

Sincerely,

Bennett N. Walker -S
Digitally signed by Bennett N. Walker -S
Date: 2021.09.20 09:14:14 -04'00'

Bennett Walker, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2008

Advanced Medical Optics, Inc.
c/o Ms. Kim Regis
Manager, Regulatory Affairs Projects
1700 E. St. Andrew Place
Santa Ana, CA 92705

Re: K081545
Trade Name: ONE SERIES™ ULTRA Cartridges
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: I
Product Code: KYB
Dated: September 25, 2008
Received: September 26, 2008

Dear Ms. Regis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CDRH INDICATIONS FOR USE

510(k) Number (if known): K081545

Device Name(s): One Series™ Ultra cartridge
Indications for Use:

Used to fold and assist in inserting TECNIS® 1-Piece intraocular lenses into the eye.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kira Alexander

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K081545

K081545

AMO®
ADVANCED MEDICAL OPTICS

OCT 02 2008

5.0 510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

1. **Submitter's name, address, telephone number, contact person, and date summary prepared:**

a. Applicant:	Advanced Medical Optics, Inc. 1700 E. St. Andrew Place Santa Ana, CA 92705
b. Contact Person:	Kim Regis Manager, Regulatory Affairs Projects 1700 E. St. Andrew Place Santa Ana, CA 92705 Ph: 714.247.8564 Fax: 714.247.8677
c. Date Summary Prepared:	May 30, 2008

2. **Name of device, including trade name and classification name:**

a. Trade/Proprietary Name:	One Series™ Ultra cartridge
b. Classification Name:	Intraocular Lens Guide
c. Device Classification:	Class I per 21 CFR 886.4300
d. Product Code:	KYB

3. **Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**

Company:	Advanced Medical Optics, Inc. (AMO®)
Device:	AMO® PhacoSert™ cartridge
510(k):	K961242
Date Cleared:	June 17, 1996

Company:	IntraLuminal Therapeutics, Inc.
Device:	Safe-Cross® Deflecting Catheter
510(k):	K031692
Date Cleared:	August 22, 2003

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

   The One Series™ Ultra cartridge is used to fold and assist in the insertion of a TECNIS® 1-Piece soft acrylic intraocular lens (IOL) into the eye following cataract extraction. The cartridge, Model 1VIPR30 is a single-use component composed of polypropylene which is injection molded and coated with a lubricious coating. The cartridge is provided sterile. The IOL is loaded into the proximal portion of the cartridge using forceps. The cartridge is then placed in a reusable titanium handpiece, which advances the IOL through the tube section of the cartridge and delivers it into the eye.

5. **Statement of intended use:**

   The One Series™ Ultra cartridge is used to fold and assist in the insertion of a TECNIS® 1-Piece soft acrylic intraocular lens (IOL) into the eye.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

   The technological characteristics of the One Series™ Ultra cartridge were compared to those of the predicate devices and were found to be equivalent with respect to materials, method of sterilization, intended use, and/or mode of operation.

7. **Brief summary of nonclinical tests and results:**

   Bench testing and biocompatibility testing were conducted which verified that the material and performance characteristics (folding, delivery, and retention of IOL cosmetic, dimensional, and optical properties) associated with the One Series™ Ultra cartridge were equivalent to that of the predicate devices.

8. **Conclusions:**

   AMO has demonstrated through its evaluation of the One Series™ Ultra cartridge that the device is equivalent to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

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Sincerely yours,

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